§170.315(b)(5) Common Clinical Data Set summary record – receive

2015 Edition CCGs

Version 1.4 Updated on 09-21-2018

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	01-05-2016
1.1	Clarification on testing and certification flexibility permitting leveraging test results from § 170.315(b)(1) for (b)(5).	04-22-2016
1.2	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	09-29-2017
1.3	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion. Note: Due to an error in calculation ONC is also updating the dates for compliance with the March 2017 Validator Update of C-CDA 2.1 Corrections that were adopted September 29, 2017.	05-02-2018
1.4	Provides notification of August 2018 Validator Update of C-CDA 2.1	09-21-2018

	Corrections adoption and compliance requirements for the entire criterion.	

Regulation Text

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§170.315 (b)(5) *Common Clinical Data Set summary record – receive—*

(i) Enable a user to receive a transition of care/referral summary formatted in accordance with the standards adopted in §170.205(a)(3) and §170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(1) The standard specified in §170.207(i).

(2) At a minimum, the standard specified in §170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only.* Discharge instructions.

(ii) *Validate and display.* Demonstrate the following functionalities for the document received in accordance with paragraph (b)(5)(i) of this section:

(A) *Validate C-CDA conformance—system performance.* Detect valid and invalid transition of care/referral summaries including the ability to:

(1) Parse each of the document types formatted according to the following document templates: Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in §170.205(a)(3) and §170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in §170.205(a)(3) and §170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display.* Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in §170.205(a)(3) and §170.205(a)(4).

(C) *Display section views.* Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in §170.205(a)(3) and §170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

Standard(s) Referenced

Paragraph (b)(5)(i)

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

§ 170.207(i) ICD-10-CM

Please refer to the Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) as outlined in the Common Clinical Data Set Reference Document

Paragraph (b)(5)(ii)

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012. The use of the "unstructured document" document-level template is prohibited.

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

Additional Resources

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012

Certification Companion Guide: Common Clinical Data Set summary record – receive

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	No

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(5). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every

capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the Consolidated CDA (C-CDA) Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62633]
- We recommend health IT developers and providers follow the guidance provided in the HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm. This Companion Guide includes industry best practices guidance for consistent implementation of the C-CDA Release 1.1 standard, including mapping Common MU Data Set elements into the C-CDA standard. [see also 80 FR 62633] We understand that HL7 is developing a Companion Guide for C-CDA Release 2.1 and intend to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C-CDA Release 2.1 standard.
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see FAQ #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. Consistent with FAQ 51, there is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., C-CDA 2.1 Validator). Similarly consistent with FAQ 51, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.
  - March 2017 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 28, 2017; Surveillance compliance date is March 29, 2019]
  - April 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on July 31, 2018; Surveillance compliance date is November 2, 2019]
  - August 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 20, 2018; Surveillance compliance date is March 21, 2020]
- At the discretion of the ONC-ATL and ONC-ACB, the requirements of this criterion may be met through testing and certification to § 170.315(b)(1).

Paragraph (b)(5)(i)

Technical outcome – The health IT can receive a C-CDA (formatted to either Release 1.1 or Release 2.1) that includes the Common Clinical Data Set, Encounter diagnoses according to either ICD-10-CM or SNOMED CT® codes, Cognitive status, and Functional status.

- Ambulatory setting only – The user is able to receive a C-CDA (formatted to either Release 1.1 or Release 2.1) that also includes the reason for referral and the referring or transitioning provider's name and office contact information.
- Inpatient setting only – The user is able to create a C-CDA (formatted to either Release 1.1 or Release 2.1) that also includes the discharge instructions.

Clarifications:

- We are requiring Health IT Modules to be able to receive C-CDAs formatted to both C-CDA Release 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62645 and 80 FR 62634]
- In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National Library of Medicine provides. [see also 77 FR 54220]
- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4
  - SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for Cognitive status and be aware that the C-CDA Validator will issue an error if the deprecated Cognitive Status Observation is used instead.

Paragraph (b)(5)(ii)(A)

Technical outcome – The health IT can detect valid and invalid ToC/referral summaries upon receipt of C-CDA documents formatted to C-CDA Release 1.1 and 2.1.

Clarifications:

- We are requiring Health IT Modules to be able to validate C-CDAs formatted to both C-CDA Release 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62645 and 80 FR 62634]
- Testing for the receipt of C-CDA Release 1.1 documents will offer two options – to test either a non-specified C-CDA document or a CCD. Health IT Modules will not be tested for C-CDA Release 1.1 Referral Note and Discharge Summary document templates. Note that Health IT Modules will be tested for receipt of all three document templates (i.e., CCD, Referral Note, and (inpatient setting only) Discharge Summary) for C-CDA Release 2.1.
- Testing for the receipt of C-CDA Release 1.1 documents will offer two options – to test either a non-specified C-CDA document or a CCD. Health IT Modules will not be tested for C-CDA Release 1.1 Referral Note and Discharge Summary document templates. Note that Health IT Modules will be tested for receipt of all three document templates (i.e., CCD, Referral Note, and (inpatient setting only) Discharge Summary) for C-CDA Release 2.1.
- Error notification should be made available to authorized users of the receiving organization who can deal with the errors as appropriate and the error may be resolved by a support analyst or end

user. [see also 80 FR 62634]
- There is no requirement that users be interrupted to be notified of errors, only that the user can access and review the errors. [see also 80 FR 62634]
- Receiving systems are not expected to translate codes from a source that has not formatted the data according to the applicable vocabulary standard required by the C-CDA Releases 1.1 and 2.1. [see also 77 FR 54220] However, receiving systems would be expected to identify data not formatted according to the applicable vocabulary standard as an error.

Paragraph (b)(5)(ii)(B)

Technical outcome – The health IT can display, for both C-CDA Releases 1.1 and 2.1, a human-readable C-CDA to a user.

Clarifications:
- No additional clarifications available.

Paragraph (b)(5)(ii)(C)

Technical outcome – The health IT allows a user to choose to display only the data within a particular C-CDA section, set a preference for the section display order, and set the initial number of sections to be displayed. This applies to both C-CDA Releases 1.1 and 2.1.

Clarifications:
- The use of the C-CDA CDA XSL style sheet will not be sufficient to meet the requirements of this provision. [see also 80 FR 62634]

Content last reviewed on June 1, 2020